

Patents

Serial No.: 10/044,275

Response Dated November 5, 2003

Response to Office Action of May 5, 2003

AMENDMENTS TO THE CLAIMS

Claims 1, 9, 10, 11, 13-15, 28 and 38 are currently amended, claims 5, 16 and 27 are withdrawn and claims 2-4, 6-8, 12, 17-26, 29-37, 39-45 remain as originally filed in the application. The following listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A dermatological delivery system comprising a topically acceptable, non-adhesive, inert support manufactured from a material selected from the group consisting of cotton, rayon, polyester, polypropylene, wood pulp, mohair, nylon fleece, and neoprene foam, or combination thereof, impregnated with a metronidazole solution with an about 0.1% to about 2% solution of metronidazole, said metronidazole solution including a major solvent component comprising water, an alcohol or a mixture of water and an alcohol, said support being operable to permit application of said solution to the skin.
2. (original) A dermatological delivery system according to claim 1 wherein said support is a woven fiber matrix.
3. (original) A dermatological delivery system according to claim 1 wherein said support is a non-woven fiber matrix.
4. (original) A dermatological delivery system according to claim 1 wherein said support is a polymeric sponge.
5. (withdrawn) A dermatological delivery system according to claim 1 wherein said support is selected from the group consisting of cotton, rayon, polyester, polypropylene, wood pulp, mohair, nylon fleece and neoprene foam, and a combination thereof.
6. (original) The delivery system according to claim 1 wherein said support is rayon and polyester.

Patents

Serial No.: 10/044,275

Response Dated November 5, 2003

Response to Office Action of May 5, 2003

7. (original) The delivery system according to claim 1 wherein the support comprises from 20%-80% rayon and from 20%-80% polyester.
8. (original) The delivery system according to claim 1 wherein the support system is 50% polyester and 50% rayon.
9. (currently amended) A dermatological delivery system according to claim 1 wherein said ~~major solvent component alcohol~~ is ~~ethanol~~ an alcohol selected from the group consisting of ethanol, isopropanol, propanol and butanol or combinations thereof.
10. (currently amended) The delivery system according to claim 9 wherein the ~~ethanol alcohol~~ is present in an amount between ~~0%-100%~~ 0%-99.5%.
11. (currently amended) The delivery system according to claim 9 wherein the ~~ethanol alcohol~~ is present in an amount of between 50%-80%
12. (original) A dermatological delivery system according to claim 1 wherein said major solvent component is water.
13. (currently amended) The delivery system according to claim 12 wherein the water is present in an amount between ~~0%-100%~~ 0%-99.5%.
14. (currently amended) A dermatological delivery system according to claim 1 wherein said major solvent component is a mixture of water and ~~ethanol~~ an alcohol.
15. (currently amended) A dermatological delivery system according to claim 1 wherein said major solvent component comprises water, ~~ethanol~~ an alcohol or a mixture of water and ~~ethanol~~ an alcohol, and at least one polyol.
16. (withdrawn) A dermatological delivery system according to claim 1 wherein the metronidazole is present in a concentration of from about 0.1% to about 2%.
17. (original) The delivery system according to claim 1 wherein the metronidazole is present in a concentration of 0.75%.
18. (original) The delivery system according to claim 1 wherein the metronidazole is present in a concentration of 1.25%.

Patents

Serial No.: 10/044,275

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Response to Office Action of May 5, 2003

19. (original) The delivery system according to claim 1 wherein the metronidazole is present in a concentration of 2.0%.
20. (original) The delivery system of claim 1 wherein the volume of said metronidazole solution delivered is from about 0.1 to about 10 ml.
21. (original) The delivery system of claim 1 wherein the volume of said metronidazole solution delivered is about 5ml.
22. (original) The delivery system of claim 1 wherein the inert support is from about 0.5 in² to about 144 in² in area.
23. (original) The delivery system of claim 1 wherein the inert support is from about 1 in² to about 4 in² in area.
24. (original) The delivery system of claim 1 wherein the inert support is from about 1 mil to about 500 mils thick.
25. (original) The delivery system of claim 1 wherein the inert support is from about 5 mils to about 250 mils thick.
26. (original) The delivery system of claim 1 wherein the inert support is from about 10 mils to about 100 mils thick.
27. (withdrawn) A dermatological delivery system comprising a topically acceptable, inert support selected from the group consisting of cotton, rayon, polyester, polypropylene, wood pulp, mohair, nylon flecce, and neoprene foam, or combination thereof, impregnated with an about 0.1% to about 2% solution of metronidazole; said solution having a major solvent component comprising water, ethanol or a mixture of water and ethanol, said support being operable to permit application of said solution to the skin.
28. (currently amended) A dermatological delivery system comprising an alcoholic or aqueous solution, or a hybrid thereof, of metronidazole in an antimicrobially effective concentration impregnated on a topically acceptable, non-adhesive, inert support which is a woven or non-woven fiber matrix or a polymeric sponge.
29. (original) The delivery system of claim 1 wherein the inert support is single use.

Patents

Serial No.: 10/044,275

Response Dated November 5, 2003

Response to Office Action of May 5, 2003

30. (original) The delivery system of claim 1 wherein the inert support is part of a multiple dosing device having a storage means for multiple doses of metronidazole.
31. (original) The delivery system of claim 30 wherein the multiple dosing device contains from 1-250 ml of metronidazole solution.
32. (original) The delivery system of claim 30 wherein the multiple dosing device is a dab-o-matic.
33. (original) The delivery system of claim 30 wherein the storage means comprises plastic, glass or metal.
34. (original) The delivery system of claim 30 wherein the storage means comprises one or more of the following: polyester, polypropylene, polyethylene, glass, steel or aluminum.
35. (original) The delivery system of claim 30 wherein the multiple dosing device is pressurized.
36. (original) A dermatological delivery system as in claim 1 in which the delivery system is packaged in a light and/or oxygen blocking barrier.
37. (original) A dermatological delivery system as in claim 36 in which the blocking barrier is selected from at least one of the following: Polyester/Polyethylene/Foil/Barex; Cellophane/Polyester/Foil/Co-extruded Polyethylene; Cellophane/Polyethylene/Foil/Poluethylene; Cellophane/Polyethylene/Foil/Surlin; Polyester/Polyethylene/Foil/Sclair; Cellophane/Polyethylene/Foil/Foil/co-polymer Paper/Poly-ethylene/Foil/PET; (polyethyleneterephthalate)/Polyethylene Paper/ Polyethylene/Foil/Co-extruded Polyethylene; Polyester/Polyethylene/Foil/Ethylene Acrylic Acetate/Polyethylene; Polyester/Polyethylene/Foil/Ethylene Methyl Acrylate Polyethylene; PET/ Polyethylene/Foil/ Barex.
38. (currently amended) A method of treating dermatological conditions comprising topical administration of an effective amount of metronidazole using a delivery system comprising a topically acceptable, non-adhesive, inert support manufactured from a material selected from selected from the group consisting of cotton, rayon, polyester, polypropylene, wood pulp, mohair, nylon fleece, and neoprene foam, or combination thereof, impregnated with a metronidazole solution with an about 0.1% to about 2% solution of metronidazole, said

Patents

Serial No.: 10/044,275

Response Dated November 5, 2003

Response to Office Action of May 5, 2003

~~metronidazole~~ solution including a major solvent component comprising water, an alcohol or a mixture of water and an alcohol, said support being operable to permit application of said solution to the skin.

39. (original) The method of claim 38 wherein the dermatological condition is any condition suitable for treatment with topical metronidazole.

40. (original) The method of claim 38 wherein the dermatological condition is rosacea.

41. (original) The method of claim 38 wherein the dermatological condition is acne.

42. (original) The method of claim 38 wherein the dermatological condition is a metronidazole susceptible infection.

43. (original) The delivery system of claim 1 having a metronidazole degradant content of less than 0.1%

44. (original) The delivery system of claim 43 wherein 2-methyl-5-nitrometronidazole is present at less than 1%.

45. (original) The delivery system of claim 43 wherein metronidazole 4-nitro isomer is present at less than 1%.